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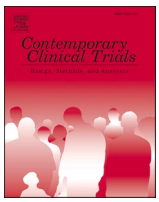

Executive control training for adolescents with ADHD: Study protocol for a randomised controlled trial

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ABSTRACT

Background: Attention-Deficit/Hyperactivity Disorder (ADHD) is one of the most prevalent neurodevelopmental conditions diagnosed during childhood and adolescence. In addition to the commonly observed symptoms of inattention, hyperactivity, and impulsivity, individuals with ADHD often experience impairments in executive functions (EFs). Goal management training (GMT) is a cognitive remediation intervention targeting EFs, with empirical support from studies with adult populations, including ADHD. The objective of the upcoming trial is to assess the effectiveness of GMT for adolescents with ADHD.

Methods: This pre-registered protocol outlines a multi-centre randomised controlled trial (RCT) comparing GMT to treatment as usual (TAU) to improve EFs. We aim to recruit 120 participants, aged 12 to 18 years, recently diagnosed with ADHD. Participants will be randomly allocated to the group-based GMT intervention in addition to TAU, or the TAU condition, through block randomisation with site stratification. GMT will be delivered in groups of four to six participants, with weekly two-hour sessions for seven weeks, complemented by separate parent and teacher sessions. TAU is standard community mental health treatment. The primary outcome measure will be parent-reported EF assessed with the Behaviour Rating Inventory of Executive Function 2 (BRIEF-2). Secondary outcomes will include ADHD symptom measures, social functioning, quality of life, and neuropsychological tests (attention span, inhibition, working memory, and visuo-motor speed). The outcome assessments will be conducted at baseline, 12 weeks, 12 months, and 24 months post-treatment.

Conclusion: The study findings will contribute to determine the effectiveness of a non-pharmacological ADHD treatment, including outcome trajectories up to 24 months post-treatment.

1. Introduction

Attention-Deficit/Hyperactivity Disorder (ADHD) is one of the most prevalent neurodevelopmental disorders, characterised by high levels of inattention, hyperactivity, and impulsivity [2]. Both epidemiologic and clinical studies implicate genetic and environmental risk factors in the aetiology of ADHD, with common genetic variants being considered to be the primary cause [14]. ADHD is more often diagnosed during childhood and adolescence than in adulthood, and affects around 5% of children and 3% of adults worldwide [61]. It has been estimated that up to 70% of individuals with ADHD have at least one other psychiatric disorder (e.g., behavioural difficulties, depression, anxiety) [6,18].

A key difficulty in ADHD concerns executive functions (EFs), which refer to a set of cognitive processes that are key to goal-directed behaviours, such as working memory, cognitive flexibility, inhibitory control, and planning [59]. EF difficulties often manifest behaviourally as challenges with e.g., regulating emotions, organising academic materials, establishing routines, and completing tasks [3]. These difficulties in EFs are often associated with emotional and social difficulties, lower academic and vocational functioning, and reduced quality of life for children and adolescents with ADHD [4,7,63]. A recent study demonstrated that childhood difficulties in EFs predicted psychopathology

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symptoms in emerging adulthood, even when controlling for the effect of ADHD symptoms [45]. Additionally, EF difficulties often persist into adulthood, and have been found to influence occupational functioning in adults with ADHD [5]. Hence, targeting EFs is crucial during early-treatment interventions.

In the mental health practice field, psychostimulant medication is frequently prescribed as a treatment option for ADHD, alongside non-pharmacological interventions such as psychoeducation, academic support and parental guidance [19,39]. While often effective for alleviating the core symptoms of ADHD, pharmacotherapy may not be sufficient to remediate EF impairments [21,25]. In addition, psychostimulant treatment can, for some individuals, be accompanied by adverse side effects, such as insomnia, loss of appetite, reduction in height and weight gain and concerns regarding potential stimulant abuse [12,13,20,39]. Consequently, many patients and/or their parents opt not to take such medications, resulting in high rates of treatment discontinuation [66]. This has prompted healthcare professionals, patients, and parents to seek non-pharmacological treatment options [49,50,57].

To date, only a small number of published studies have focused on psychological interventions for adolescents diagnosed with ADHD. Vidal et al. [74] investigated the effect of group-based CBT sessions on adolescents within the age range of 15 to 21 years and reported significant improvements in ADHD symptoms compared to the waiting list control group. However, a limitation of this study was the exclusion of participants with comorbid disorders. On the other hand, Haugan et al. [23] reported no incremental treatment effect of group-CBT as a follow-up to psychoeducation and pharmacological treatment on ADHD symptoms as well as general psychosocial functioning. The authors of this study identified the lack of parental involvement during treatment as a noteworthy limitation that potentially influenced the treatment response [23].

Cognitive remediation training has also been investigated as a potential non-pharmacological treatment option for ADHD. These interventions often employ metacognitive strategies, self-monitoring, and error management to address challenges in attentional control, working memory, and inhibitory control [11]. A systematic review of 121 studies on evidence-based cognitive remediation in acquired brain injury populations found promising results regarding patients' ability to set and accomplish goals, and effectively manage a series of real-life tasks after training [10]. However, the authors note that previous studies often depend solely on therapists' ratings, and the absence of masked outcome assessments limits the interpretation of the results thus far [10].

In summary, a recent meta-analysis of 18 studies examined the neuropsychological effects of non-pharmacological interventions in individuals with ADHD across different age groups, including children, adolescents, and adults [35]. This analysis encompassed various interventions such as physical exercise, cognitive behavioural therapy (CBT), cognitive training, neuro- and biofeedback training, all of which demonstrated moderate to large effect sizes on attention, inhibition, flexibility, and working memory [35]. While this meta-analysis highlighted the positive impact of psychological interventions on ADHD-related outcomes, its generalisability is highly limited due to the small number of included studies conducted in the field. However, similar results were also reported in a newer meta-analysis by Qiu et al. [47], which included 67 studies. This meta-analysis investigated the effects of cognitive training, game-based training, mindfulness practice, neurofeedback training, and physical exercise, demonstrating significant moderate to large effects on overall EF in children and adolescents with ADHD [47]. Despite the evidence supporting psychological interventions for ADHD, the clinical utility of the outlined interventions is still limited, particularly for adolescents [43,47].

To address the research gaps previously mentioned, as well as those outlined in Table 1, the main aim of this upcoming RCT is to test a cognitive remediation intervention, called Goal Management Training (GMT), that directly targets attention and EFs [38]. The GMT intervention will be administered in a group-based format for the participating adolescents, with active involvement from both their parents and teachers [9]. The study will be conducted within clinical practice settings, involving multiple centres, and will include participants with comorbid disorders over a follow-up period of two years to better determine the effectiveness of the treatment.

Table 1
Addressing previous research limitations in the upcoming RCT.

Previous research limitations	Solutions implemented in our project
No or non-active control groups [68]	Includes TAU control group.
Lack of randomisation [68]	Randomises participants to treatment group (GMT) or TAU through block randomisation with site stratification.
Lack of parental involvement and low relevance for primary care [23,68]	Includes training of parents and teachers, as well as between-session assignments, to facilitate the transfer from training to real life.
Lack of related health indicators, such as social relationships, behavioural problems, and academic achievement [47]	Includes daily life EF as the primary outcome measure, along with mental health symptom questionnaires, social functioning ratings, quality of life inventories, and measures of physical, emotional, social, and school functioning as secondary outcome measures.
Lack of consideration of comorbidity [68]	Includes participants with comorbidities. Uses standardised baseline and post-assessment of comorbidity.
Lack of consideration of confounders [68]	Assesses client motivation and perceived treatment credibility. Considers clinician, parent, and adolescent reported mental health as potential mediator/moderator of effectiveness.
Lack of masked outcome assessment ([10]; [68])	Assessments and neuropsychological outcomes will be conducted by research assistants who are masked to the study conditions.
Missing follow-up data [68]	Psychometric questionnaires will be completed online, and participants will receive a small reward for participating in follow-ups.
Lack of power [68]	Power calculation-based sample of $N = 120$.
Effects on cognition limited to laboratory tasks [35]	Measures from laboratory tasks, neuropsychological tests, clinical interviews, as well as parent, self, and teacher reports.
Lack of data availability and transparency	Supports and complies with established Open Science practices to promote transparency and reproducibility.
Lack of understanding of ADHD in girls [73]	Examines sex differences in neuropsychological functioning.

GMT is a manualised cognitive remediation intervention that utilises metacognitive strategies to enhance executive and attentional processes [38,64]. It focuses on mechanisms of inhibitory control by teaching problem-solving skills, inhibition strategies, and mindfulness techniques, making it a suitable approach for individuals with ADHD [3,37]. Approximately 80 studies have documented the efficacy of GMT on adult patients with traumatic brain injury, spina bifida, multiple sclerosis, stroke, post-traumatic stress disorder (PTSD) affective disorders, as well as adults with ADHD [22,62].

GMT has yet to be tested on adolescents with ADHD, but a paediatric version of the GMT manual for children and adolescents has been developed and tested with promising results ([9]; R. [27,54]). Moreover, a recent study showcased encouraging outcomes using a GMT-based program for adolescents with executive dysfunction complaints [42]. As it can be argued that executive dysfunction is a transdiagnostic symptom [16,52], GMT could be adapted and applied across various aetiologies and disorders, such as ADHD.

The primary goal of our RCT is to assess the effectiveness of GMT as a group-based non-pharmacological intervention, in addition to treatment as usual (TAU) for adolescents recently diagnosed with ADHD.

Additionally, we aim to investigate potential transfer effects of the interventions on affective symptoms, social functioning, and quality of life. Thus, we have formulated the following hypotheses: 1) GMT in addition to TAU, will be more effective than TAU in improving EFs in adolescents with ADHD. Post-intervention changes after 12 weeks will be reflected in significantly improved scores on parent-reported EF, using the Behaviour Rating Inventory of Executive Function 2 (BRIEF-2), compared to the TAU condition. 2) Emotional health, social functioning and quality of life will be significantly higher following GMT, when compared to the TAU condition.

We will also explore which clinical symptoms and/or cognitive functions are associated with treatment response, as follows: 3) We expect that adolescents with primarily EF impairments and minimal comorbidity will experience the greatest benefits following GMT, as the program is specifically designed to target EF difficulties. Additionally, we have introduced an exploratory research question without a predefined hypothesis to advance the current knowledge in the field: 4) To what extent do medication, age, gender, and functional status at the time of enrollment influence short-term (12 weeks) and long-term (12 months and 24 months) treatment outcomes?

2. Materials and methods

2.1. Study design

The outlined parallel RCT will be using a repeated-measures design across four time points: baseline (T1), 12 weeks post-intervention (T2), 12-month follow-up (T3), and 24-month follow-up (T4), as shown in Fig. 1. Participants in the GMT condition will also receive standardised treatment for children and adolescents with ADHD as recommended by the Norwegian Directorate of Health [41].

2.2. Study setting and timeline

The trial is a multi-center RCT conducted at the child and adolescent psychiatric outpatient clinic at Lovisenberg Diaconal Hospital in Oslo, Norway, in addition to Innlandet Hospital Trust at Hamar and Gjøvik, Norway. The inclusion of participants and administration of the interventions will be implemented concurrently across all three sites. Data collection is estimated to begin September 2023 and to be completed by December 2026.

2.3. Interventions

2.3.1. Goal management training

GMT is a manualised cognitive remediation intervention derived from clinical and neuroscientific research on attention and executive control [51]. GMT teaches individuals how to focus on task objectives, monitor outcomes, and evaluate their performance as they progress [51]. The training includes learning strategies to construct goal hierarchies, stop ongoing activity ("STOP!-and-think") to orient towards relevant goals, and assess whether their behaviour aligns with these objectives [38,64]. Additionally, the program incorporates elements of mindfulness training to help participants develop the necessary skills to stay present and maintain focus on the task at hand [30,36].

A paediatric GMT protocol was developed and piloted by Stubberud et al. [65] and then further revised by Brandt et al. [9]. For our RCT, the manual has been further revised and adapted, based on feedback from a user representative, with minor modifications to cater to the needs of adolescents with ADHD. The changes primarily involved making examples more relevant to an ADHD sample, simplifying the language, and reducing the amount of text. The GMT groups will be led by two mental-health clinicians at each site, who are associated with our study. GMT consists of 14 h of training in groups of 4–6 participants, over the course of 7 weeks (one 2-h session per week), as shown in Table 2.

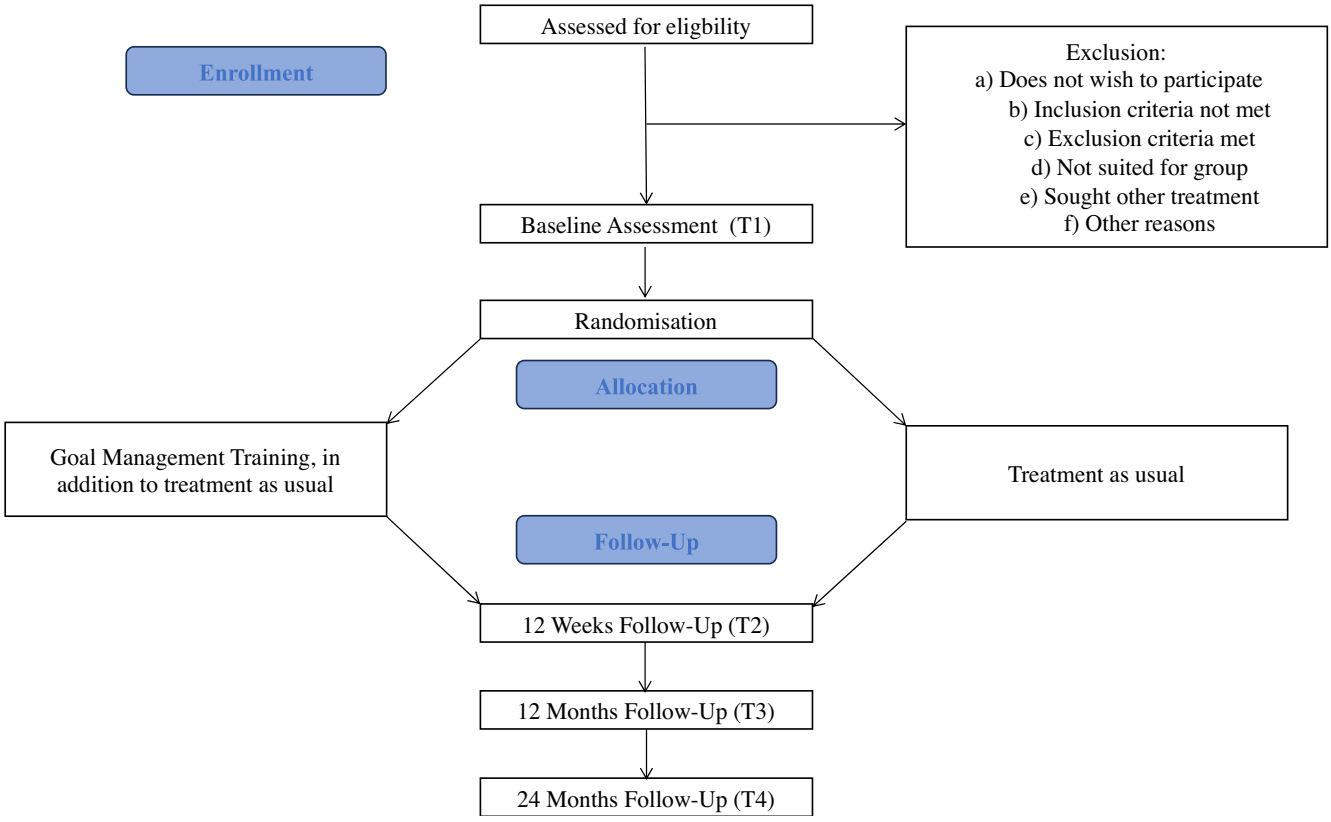

Fig. 1. Study flowchart.

Table 2
GMT session description and objectives.

GMT Session	Description and objectives
Session 1: The Present and the Absent mind	The concepts of absent-mindedness and present mindedness are introduced. Absentminded slips are tracked between sessions, and a mindfulness technique ("present-mindedness") exercise is used to illustrate present-mindedness.
Session 2: Absentminded Slip-Ups	Conditions for and consequences of absentmindedness slips are discussed. The monitoring of slips continues, and a 'breathing exercise' is introduced and practiced between sessions throughout the training."
Session 3: The Automatic Pilot "stop"	The concept of the 'automatic pilot' and its potential to result in inappropriate responses is discussed. Situational factors that elevate the risk of slips are mapped. Participants are encouraged to develop the habit of 'STOPPING!' the 'automatic pilot,' redirecting attention to the present moment, and monitoring ongoing behaviours and thoughts.
Session 4: The Mental Blackboard	The concept of 'the mental blackboard,' a metaphor for working or short-term memory with limited capacity and content that can be easily displaced, is introduced. The STOP!-FOCUS-CHECK technique is used stop automatic pilot, to bring attention to the present, and to direct attention to the main goal.
Session 5: State Your Goal	The notion of STATING one's goal is introduced to reduce slips and facilitate goal maintenance. STOP! -STATE cycle is practiced, using a breathing exercise to bring the mind back into the present and restate the goal.
Session 6: Splitting Tasks into Subtasks	Splitting overwhelming tasks into subtasks (The STOP! -STATE-SPLIT technique) is discussed and practiced both within and between sessions.
Session 7: Checking (STOP!)	Checking, which involves reducing slip-ups by adapting behaviour to situational changes and maintaining goal monitoring, is thoroughly discussed, and practiced. STOP! and CHECK is reemphasised. The training concludes with a summary of the GMT program.

The sessions are accompanied by PowerPoint slides and participant workbooks. Participants will also be given homework assignments that include practical exercises and logging of activity (monitoring): e.g., logs of absentmindedness, present-mindedness practice, and practice on "stop-and-think" strategies. After sessions 2, 4, and 7, the parents of the participants will have dedicated group-sessions with the GMT therapists to introduce and review session materials. Additionally, two 1-h GMT telephone counselling sessions with the participants' teacher will be conducted at the beginning and following the intervention phase, emphasising how the strategies can be used in a school setting.

2.3.2. Treatment as usual

The TAU condition in the upcoming trial is based the National Institute of Health and Clinical Excellence (NICE) clinical guidelines for ADHD assessment and treatment, established by the Norwegian Directorate of Health [41]. These clinical guidelines emphasise psychoeducation, parent- and school counselling, as well as pharmacological treatment adapted to the needs of each patient [41]. In the upcoming RCT, all participants will receive TAU, and clinicians will use a checklist to record the treatment elements that each participant receives.

2.4. Sampling and eligibility criteria

2.4.1. Inclusion criteria

(1) Adolescents who have been diagnosed with ADHD, according to the criteria in the Diagnostic and Statistical Manual of Mental Disorders V (DSM-V) [2] by mental health professionals at each site.
(2) Aged 12–18 years.

We aim to include participants irrespective of their concurrent pharmacological treatment. Stable type and dosage will be required for at least six weeks before and throughout participation. While we encourage families not to alter ADHD medication during the the trial, we will control weekly for any changes that may occur.

The standardised procedure for assessing and diagnosing ADHD follows the national guidelines [41], which closely align with the National Institute for Health and Care Excellence (NICE) guidelines [40]. During the diagnostic evaluation, in-person interviews with adolescents and parents using the Schedule for Affective Disorders and Schizophrenia for School Age Children/Present and Lifetime version- (K-SADS-PL) [31] will be used to identify ADHD and comorbid conditions. Relevant information concerning neurological conditions will also be obtained from the patients' medical records. Participants' scores from the Wechsler Intelligence Scale for Children – Fifth Edition (WISC-V) [70], or the Wechsler Adult Intelligence Scale – Fourth Edition (WAIS-IV) [69], will be induced and controlled for in a subsection of the analysis.

2.4.2. Exclusion criteria

The exclusion criteria are:

(1) Severe depression, suicidality, psychosis, bipolar disorder without stable medication and current substance abuse.
(2) Organic brain injury or diagnosed neurological disorders.
(3) Cognitive or medical impairments that make it difficult to attend regular school.

2.5. Recruitment procedure

Our goal is to recruit a minimum of 120 adolescents over a three-year period, distributed across the three different sites. Prior to enrolment, all participants (over the age of 16), and their parents will be required to provide their electronically signed written informed consent. This consent will be obtained through identification using their social security number and BankID, which is the commonly used digital identification method for public services in Norway.

2.6. Randomisation

All participants assessed for eligibility who have given their consent to participate in the study will be completing the baseline assessment (T1) prior to randomisation. After the baseline assessment, participants will be assigned in a 1:1 ratio to either TAU or GMT in addition to TAU using a computerised randomisation program for parallel group randomised trials (https://www.randomizer.org) employed by an independent researcher. Block randomisation with a block size of four and stratification by the three sites will be implemented to guarantee even distributions among the experimental groups over the course of the study.

2.7. Outcome measures

2.7.1. Primary outcome measure

The primary outcome measure is parent-reported daily life EFs, assessed using the Behaviour Rating Inventory of Executive Function, Second Edition (BRIEF-2) [17]. The BRIEF-2 offers a comprehensive assessment of EFs consisting of 63 items that measure inhibition, self-monitoring, shift, initiation, working memory, emotional control, planning, task-monitoring, and organisation of materials. These primary scores are then combined to form three separateindices consisting of Behaviour Regulation Index (BRI), Emotional Recognition Index (ERI) and Cognitive Regulation Index (CRI), as well as a unitary Global Executive Composite (GEC), which will be used for the primary analysis in this RCT.

The BRIEF-2 is applicable to several clinical groups, providing high

ecological validity, a Cronbach's alpha coefficients ranging from 0.90 to 0.97, and a 3 weeks test–retest reliability ranging from 0.67 to 0.92 (M = 0.79) in the normative sample [24]. Given that parents possess the unique vantage point of observing their children's behaviours and abilities in their home environment, the BREIF-2 measure was deemed suitable for our study's objectives. The BREIF-2 parent version has also been utilised as an outcome measure in previous GMT studies on children, facilitating a more direct comparison of our results with the existing literature [26,65]. BRIEF-2 will be collected at baseline (T1), 12 weeks follow-up (T2), 12 months follow-up (T3) and 24 months follow-up (T4).

2.7.2. Secondary outcome measures

Secondary outcome measures include self-reported BRIEF-2 scores, collected at all timepoints (T1-T4), as well as teacher-reported BRIEF-2 scores at T1, and T2 [17]. Severity of ADHD symptoms will be assessed during T1, T2 and T4 using the ADHD Rating Scale Version IV (ADHD-RS-IV) [15]. Mental health symptoms will be assessed using the self- and parent report of the Achenbach System of Empirically Based Assessment (ASEBA) [1] measured at T1, T2 and T4. Social functioning evaluated by the self and home report of the Weiss Functional Impairment Rating Scale [71] at T1, T2 and T4. Paediatric Quality of Life Inventory (PedsQL) will be used to assess physical, emotional, social and school functioning during T1, T2 and T4 [67].

Participants will also complete a performance-based neuropsychological test battery for iPad named CABPad (Cognitive Assessment at Bedside for iPad) developed by neuropsychologist Palle M. Pedersen at Cognisoft ApS, both at T1 and T2. This test battery includes assessments for verbal fluency, attention span, inhibition, working memory, and visuo-motor speed, and has shown a high correlation with other neuropsychological tests within the same domains [72].

To assess participants' perception of treatment efficacy in daily life goal attainment, Goal Attainment Scaling (GAS) [33] will be used at baseline and during the 12-week follow-up. Furthermore, we will assess overall functioning at T1 using the Children's Global Assessment Scale (CGAS) [56]. To identify other variables that might be associate with treatment response, we also will register demographic (e.g., parent socioeconomic status), clinical (e.g., psychiatric comorbidities), and cognitive (e.g., intelligence, learning disabilities) characteristics gathered from the patients' health registries at the respective hospitals, prior to the implementation of GMT. Following randomisation, as an addition to the baseline assessments, we will administer two modified measures to evaluate participants' motivation, utilising the Nijmegen Motivation List [32], along with an adapted version of a credibility scale to assess participants' anticipated treatment effects [8].

All clinical assessments at baseline will be conducted by PhD/postdoc researchers, and supervised test assistants. Subsequent follow-up assessments will be conducted by research assistants who are masked to the study conditions. Table 3 provides an overview of all the respective outcome measures.

Table 3
List of measures employed at each measurement point.

Variable	Rater	Mode	$T1^{0W}$	$T2^{12w}$	$T3^{12m}$	$T4^{24m}$
Sociodemographic data: Gender, age, education status, parental education.	R	Patients' health records	X			
Behaviour Rating Inventory for Executive Functions (BRIEF-2)	P/T*/A	Digital form	X	X	X	X
Weiss Functional Impairment Rating Scale	P	Digital form	X	X	X	X
ADHD Rating Scale IV	P/T*	Digital form	X	X	X	X
Achenbach System of Empirically Based Assessment (ASEBA)	A/P	Digital form	X	X	X	X
Paediatric Quality of Life Inventory (PedsQL)	A/P	Digital form	X	X		X
Goal Attainment Scaling (GAS)	A&IO	Clinical interview	X	X	X	X
Global Assessment of Functioning-Split Version (CGAS)	IO	Rating	X			
CABPad	A&IO	IPAD	X	X		
Nijmegen Motivation List	A/P	Digital form	X			
Credibility Scale	A/P	Digital form	X			

Note. P = parent, T* = teacher (will only be measured at $T1^{0w}$ and T^{12w}), A = adolescent, R = researcher, IO = independent observer (masked).

2.8. Sample size justifications and power calculations

The intended sample includes 120 adolescents, with 60 participants in each condition. A priori sample size calculations were conducted using a repeated-measures analysis of variance indicated the necessity of 60 participants per group to detect an effect size of 0.30 with a statistical power of 84% at a significance level of $p < 0.05$ [34]. For missing data, a full-information maximum likelihood method will be estimated, assuming the missing data adhere to the missing at random assumption [53].

2.9. Statistical analysis

The statistical analysis will be conducted in R [48] and IBM SPSS Statistics (Version 27). To accommodate the data's structure, which includes repeated measurements nested within participants, we will rely on multilevel models (MLM). Our analysis will involve main effect models to quantify the difference in effect sizes between the GMT in addition to TAU, and TAU condition at the 12-week post-treatment assessment. Fixed effects will incorporate outcome predictors. The models will also include varying effect structures justified by the design, allowing the predictors of interest and the effect of time (T1-T4) to vary by patients, thereby accounting for potential variability across participants.

2.10. Ethical considerations

We perceive the potential risks to participants as minimal. All parents and participants (over the age of 16 years) must give a formal written consent, and the consent forms will explicitly state that opting not to participate will not impact their access to other services or treatment alternatives, and families retain the prerogative to withdraw from the trial at any point. Participation might be tiresome for certain participants, given that they will be required to complete multiple questionnaires and tests. Participation will additionally necessitate adolescents and their parents to allocate time away from school and work to attend the group sessions at their respective hospitals. Participants will receive a USD25 gift card for follow-ups at T2, T3, and T4. We believe this small financial incentive will enhance attendance, at the same time, this incentive is not large enough to force participants to take part if they do not wish to do so.

For the adolescents, there is the possibility that the ADHD diagnosis could elicit discomfort. Some adolescents may prefer not to be associated with the condition. Interactions within a group setting that includes other adolescents with ADHD could entail both advantages and disadvantages. The challenges include the risk of encountering social stigma, while the rewards encompass the potential for enhanced social support. Notwithstanding these considerations, our assessment leads us to

conclude that the prospective benefits hold greater significance than the potential risks involved in participating in the study.

The trial has been registered at clinical.trials.gov (identifier: NCT05874791) and has been approved by the Regional Committees for Medical and Health Research Ethics (REK), South-Eastern Norway (identifier: 420217). All data will be stored in the secured "Services for Sensitive Data" (TSD), hosted by the University of Oslo. The study will be conducted in accordance with the Helsinki declaration [29], and the Ethical Research Involving Children [46]. Lastly, the trial will be reported in accordance with the CONSORT 2010 statement [55].

3. Discussion

With this upcoming RCT, we intend to overcome some of the limitations of previous research by incorporating a robust study design, utilising a power analysis-based sample size, employing multiple and diverse outcome measures (e.g., the assessment of daily life EFs, symptom measures, social functioning, quality of life, and neuropsychological tests), implementing a long-term follow-up period of two years, and adopting GMT as a validated, theory-driven treatment strategy. This study addresses young patients with EF difficulties that influence various aspects of their daily lives, and often persist into adulthood [44,58,60]. As a result, it becomes crucial to provide accessible and effective treatment options for both them and their families [57]. If this project yields positive results, it could provide substantial evidence to endorse GMT as a cost-efficient, group-oriented intervention for adolescents with ADHD.

3.1. Limitations

One limitation of the study design is that the group receiving GMT concurrently will undergo standardised treatment (TAU). This dual-treatment approach, while reflective of real clinical scenarios, might restrict our ability to attribute observed effects solely to the GMT intervention, as we will only be able to draw conclusions on GMT in combination with TAU. However, within this study's design, the efficacy of TAU on EFs will also be analysed, as it is an outcome that is highly relevant for multiple stakeholders (adolescents, parents, mental health professionals, and health authorities). Through the inclusion of patients with 1) no history of pharmacological treatment or 2) concurrent pharmacological treatment, we will be able to investigate whether current treatment and treatment response may be associated with response to GMT.

3.2. Risks

Our study's design prompts us to acknowledge potential challenges that could affect the research outcomes. Due to the multi-site nature of the RCT, there's a latent risk of recruitment delays due to operational intricacies across sites. To ensure coordination, regular meetings will be held among the researchers at each site. The study also involves multiple follow-up assessments over two years, posing a risk of participant dropout and missing data due to time constraints and logistical issues. To counter this, all questionnaires at 12- and 24 months follow-up will be completed online. In addition, the main effect of the RCT will be measured as the effect size difference between the GMT treatment condition and the TAU condition at 12 weeks post-treatment. The advantages of this relatively early outcome assessment include early detection of effectiveness (or non-effectiveness) and lower risk of study dropout.

4. Conclusion

The implications of this upcoming RCT's outcomes are multifaceted and hold the potential to substantially shape the course of future research, clinical practices, and health policy formulation. The research findings could establish an evidence-based, non-pharmacological treatment approach for adolescents with ADHD. This, in turn, allows clinics to offer this therapeutic alternative as a supplementary choice for families who may have received limited interventions. The results might also enhance our understanding of ADHD and comorbid symptoms and could potentially improve young patients' life-long functioning.

CRediT authorship contribution statement

Agnete Dyresen: Methodology, Writing – original draft, Writing – review & editing, Investigation. **Jan Stubberud:** Conceptualization, Supervision, Writing – review & editing, Funding acquisition. **Krister Westlye Fjermestad:** Conceptualization, Funding acquisition, Supervision, Writing – review & editing. **Ingvild Haugen:** Conceptualization, Writing – review & editing. **Merete Glenne Øie:** Conceptualization, Funding acquisition, Project administration, Supervision, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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